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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,382	04/08/2004	Matthew Peterson	TPIP039	8458

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TRANSFORM PHARMACEUTICALS, INC.
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LEXINGTON, MA 02421

EXAMINER	
CHANG, CELIA C	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,382	PETERSON ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-49* is/are pending in the application.

4a) Of the above claim(s) *10-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *22-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment and response filed by applicants dated Aug. 23, 2005 have been entered and considered carefully.

Claims 1-9 have been canceled. Claims 10-21 stayed withdrawn. Claims 22-49 newly added are pending.

2. The rejection of claims 1-6 under 35 USC 103(a) over Augart et al. '482 in view of Berge et at. is now applicable to the newly added claims 22-24, 30-34, 40-43, 48-49 and maintained for reason of record.

Applicants argued that skilled person in the art such as Davis et al. will recognize that pharmaceutical addition salts would have different characters therefore each salt is a different compound. Such argument does not obviate the established prima facie case of obviousness. Please note that it was clearly taught by the Berger reference of all the different properties of the pharmaceutically acceptable salts which will "behave quite differently because of the physical, chemical and thermodynamic properties" (see p.2 lest column last paragraph) and "The salt form is known to influence a number of physical chemical properties of the parent compound including dissolution rate, solubility, stability....." (see p.5 lest column last paragraph). Therefore, the difference of pharmaceutically acceptable salts as disclosed in Davis et al. is expected as clearly disclosed by Berge. The motivation of choosing tartrate, maleate or edysilate of the instant claims was found in that they are all FDA acceptable salt as compared to the FDA non-acceptable salts as clearly suggested by Berge between table I and table II. It is well recognized that those salts such as oxalate of the FDA non-acceptable choices have undesirable properties (see CA 91:69601 i.e. oxalate has renal toxicity). Therefore, the explicit listing of the "desirable" FDA approved addition salts is a clear suggestion for one skilled in the art to pick and choose. The mere knowledge that some salt may have different property even develop toxicity does not negate the "obvious" choice of tartrate, maleate or edysilate as suggested by the FDA acceptance. In the previous office action it has been clearly delineated that the drug gabapentin is **known;** a **FDA acceptable salt** gabapentin hydrochloride has been prepared and known to be operable; clear suggestion by conventional teaching in the art that in

addition to hydrochloride, the other desirable FDA approved salt forms include tartrate, maleate or edysilate; thus, both enablement and suggestion were found in the prior art. Indication of some degree of unpredictability does not per se rebut an established prima facie case of obviousness in absence of vis-à-vis comparison showing unexpectancy. In re Wilder 195 USPQ 426.

3. The rejection of claims 1-9 under 35 USC 103(a) over Augart et al. '482 in view of Berge et at. further in view of US pharmacopia and Rouli, is now applicable to the newly added claims 22-49 and maintained for reason of record.

The same argument by applicants and its non-persuasiveness as delineated supra is hereby incorporated by reference.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Nov. 2, 2005

Celia Chang
Primary Examiner
Art Unit 1625